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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

20-668/S-003

Correspondence



DEPARTMENT OF HEALTH & HUMAN SERVICES

DF

Food and Drug Administration
Rockville MD 20857

APR 22 1999

NDA 20-668/S-003

Astra Pharmaceuticals, L.P.
Attention: Eric Couture, Ph.D.
725 Chesterbrook Blvd.
Wayne, PA 19087-5677

Dear Dr. Couture:

We acknowledge the receipt of your January 15, 1999 submission containing final printed labeling in response to our October 28, 1999 letter approving your supplemental new drug application for Lexxel (enalapril maleate/felodipine ER) Tablets.

We have reviewed the labeling that you submitted in accordance with our October 28, 1999 letter, and we find it acceptable.

If you have any questions, please contact:

Mr. David Roeder
Regulatory Health Project Manager
(301) 594-5313

Sincerely yours,

/s/

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc:

Archival NDA 20-668

HFD-110/Div. Files

HFD-110/D.Roeder

HF-2/Medwatch (with labeling)

HFD-101/ADRA (with labeling)

HFD-40/DDMAC (with labeling)

HFD-95/DDMS (with labeling)

HFD-613/OGD (with labeling)

HFD-735/OPDRA (with labeling)

DISTRICT OFFICE

Drafted by: dlr/April 2, 1999

Initialed by: F Zielinski/4/6/99

K Srinivasachar/4/6/99

W Link/4/6/99

C Duarte/4/6/99

A Karkowsky/4/6/99

N Morgenstern/4/6/99

final:sb/4/7/99

filename: 20668SOO3AR.DOC

ACKNOWLEDGE AND RETAIN (AR)

**DIVISION OF CARDIO-RENAL DRUG PRODUCTS
FOOD AND DRUG ADMINISTRATION**

AUG 19 1998



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Transmitted to FAX Number: 610-695-1828

Attention: Judy Molt

Company Name: Astra U.S.A.

Phone: 610-695-1524

Subject: Labeling comments for NDA 20-668/S-003

Date: 8/19/98

Pages including this sheet: 2

From: David Roeder
Phone: 301-594-5313
Fax: 301-594-5494

cc: NDA 20-668
HFD-110
HFD-110/DRoeder

1 pages redacted from this section of
the approval package consisted of draft labeling